DEPARTMENT OF HEALTH AND HUMAN SERVICES

JUN 22 2000

Ms. Loretta A. Mooney
Director of Quality and Regulatory Affairs
Prizm Medical, Inc.
3400 Corporate Way, Suite I
Duluth, Georgia 30096

Re: Docket No. 00P-1290
Neuromuscular Electrical Stimulators

00P 1290 '00 JUN 26 A8:40

Dear Ms. Mooney:

This responds to your citizen petition, dated May 1, 2000, requesting a exemption from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) as it applies to approximately 200 muscle stimulators returned to your firm from dealers. The devices have non-compliant 2.5 mm phono plugs that connect the lead wire to the muscle stimulator. The devices are intended for use, both in clinics and in the home. You proposed to refurbish the devices, retaining the non-compliant lead wires, and sell the units at a discount to user facilities. You would provide an opportunity for the user facility to return their device at a later date to be upgraded for a fee.

I am denying your petition because an adapter and a lead wire solution is readily available from your current lead wire supplier. A member of our staff has spoken with a representative from Plastics One. He confirmed that they have an adapter suitable for converting a 2.5 mm phono plug to a compliant lead wire connector. The information you provided regarding the extensive design changes made in September 1999 for your new device is irrelevant to the issue of converting older devices. If you wish, you may also choose to do a more extensive upgrade of these older devices to accommodate your current lead wire connector, but that would be your own business decision. It is not mandated by the performance standard. However, since there is a readily available adapter solution, you must install compliant lead wires during your refurbishment, and prior to reselling the muscle stimulator.

I note that you also mentioned a 2.0 mm pin. Your drawings show a 2.5 mm phono plug at the end where the lead wire plugs into the device, and a 2.0 mm (0.080 inch) straight pin at the end closest to the patient. Be aware that the performance standard applies only to the end of the lead wire that is remote from the patient. Therefore, the 2.0 mm pin should be a moot issue.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

PDN 1

00P-1290

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-1	KAHAN	6/22/00						

cc:
HFA-224
HFA-305 (Docket No. 00P-1290)
HFR-SE100
HFZ-1
HFZ-215 (JSheehan, MHanna, Files)
HFZ-141 (RWalchle)
HFZ-300
HFZ-305 (Precedent Correspondence)
HFZ-340 (SCrumpler))
HFZ-341
HFZ-450 (BZimmerman)

Draft:ESCrumpler:5/31/2000
Review:CEUldriks:6/1/2000
Init:Jsheehan:6/7/00
F/t:CFrye:6/20/00
Prizm Medical.ltr